

What is claimed is:

1. A whole blood immunoassay comprising the steps of:
mixing a whole blood sample with sensitized insoluble
carrier particles to cause an immune agglutination;

5 diluting the resulting agglutination mixture with an
aqueous solution containing an erythrocyte lysing agent to lyse
erythrocytes, thereby preparing an assay sample; and
determining a degree of agglutination of the assay
sample.

10 2. A whole blood immunoassay according to Claim 1,
wherein the erythrocyte lysing agent is a surfactant.

3. A whole blood immunoassay according to Claim 2,
wherein the surfactant is sodium dodecyl sulfate.

4. An whole blood immunoassay according to Claim 1
15 which is conducted by use of an apparatus for a counting
immunoassay utilizing a principle of flow cytometry.

5. A whole blood immunoassay according to Claim 4,
further comprising the steps of:

introducing the assay sample included unagglutinated
20 particles and agglutinated particles to a flow cell, irradiating
particles passing through the flow cell with laser light, and
detecting scattered light generated thereby;

setting a threshold value for distinguishing
unagglutinated particles from agglutinated particles with
25 regard to intensity of the scattered light; and

distinguishing and counting the unagglutinated particles and the agglutinated particles in reference to the threshold value; and

calculating the degree of agglutination from the
5 number of unagglutinated particles and the number of agglutinated particles.

6. A whole blood immunoassay according to Claim 5, wherein the degree of agglutination is calculated by the number of agglutinated particles P / (the number of
10 agglutinated particles P + the number of unagglutinated particles M).

7. A whole blood immunoassay according to Claim 5, wherein the scattered light is forward scattered light.

8. A whole blood immunoassay according to Claim 1,
15 wherein the size of the insoluble carrier particles is $0.1 \mu\text{m}$ to $20 \mu\text{m}$.

9. A whole blood immunoassay according to Claim 1, wherein a mixture ratio of the whole blood sample to the insoluble carrier particles is 1 :5 to 1 : 20.

20 10. An immunoassay according to Claim 1, wherein, in the immune agglutination of the whole blood sample with the insoluble carrier particles, the reaction temperature is from 20 to 50°C and the reaction time is from 15 seconds to 20 minutes.